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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/704,319 | 11/02/2000 | Hiroo Kumagai | 1514-00 | 4918 |

35811 7590 04/08/2004

IP DEPARTMENT OF PIPER RUDNICK LLP
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| EXAMINER | |
|---|---|
| LANDSMAN, ROBERT S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/704,319 | KUMAGAI ET AL. | |
| | Examiner | Art Unit | |
| | Robert Landsman | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,4,6,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 11/2/00 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/03 has been entered.

***1. Formal Matters***

A. Claims 1, 3, 4, 6, 12 and 13 are pending in the application.

B. All Statutes under 35 USC not found in this Office can be found, cited in full, in a previous Office Action.

***2. Sequence Requirements***

A. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) – see Tables 1 and 2 of the specification. However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Applicant needs to provide **a computer readable form** (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, **a paper copy** of that "Sequence Listing", **an amendment directing the entry of that paper copy into the specification**, and **a statement that the content of the paper and computer readable copies are the same** and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be **amended** so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular **sequence identifier** (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

***3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

A. Claims 1, 3, 4, 6, 12 and 13 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 7/01/03. Applicants have provided no new arguments. Generally, the rejection states that Applicants are only enabled for a method of examining pruritis in a patient undergoing hemodialysis by measuring β-endorphin (μ-peptide), Leu-enkephalin (δ-peptide) and dynorphin A (κ-peptide) levels in peripheral blood. The Office Action also states that Applicants are not enabled for examining all diseases by measuring all opioid peptides from any blood cell, body fluid or tissue other than peripheral blood.

The breadth of the claims is excessive with regard to Applicants claiming measuring any and all μ – or δ-opioid peptides, or nociceptin, in any blood cell, body fluid, or tissue. It is clear that μ-opioid (β–endorphin), or δ-opioid (enkephalin) peptides are involved in itching, for example as seen on page 3, lines 10-12 of the specification, and it would be expected that measuring the concentration of either of these peptides to a κ-opioid peptide would allow one to determine opioid-based pruritis. However, Applicants have not provided any guidance or working examples that determining any κ:κ ratios, including that involving nociceptin, would be indicative of an opioid-based pruritis, nor would this conclusion be predictable in absence of this guidance or working examples.

The breadth of the claims is also excessive with respect to Applicants calculating opioid peptide ratios in any component other than peripheral blood. Applicants have provided no guidance or working examples that determining opioid ratios in blood cells, body fluids, or tissue would be indicative of a pruritis-based disease. It is not known how, for example, measuring peptide concentrations in lymph or aqueous humor (body fluids), in the liver (tissue), or in a platelet (blood cell) would be indicative of pruritis in the hand. Applicants have only demonstrated (Example 2 of the specification) that opioid peptide levels in peripheral blood (i.e. serum) would be indicative of pruritis. Without further guidance, it would not be predictable to the artisan that the ratio of opioid peptides in all blood cells, body fluids or tissue can be used to examine or diagnose opioid-based pruritis.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming measuring any and all κ opioid peptides (κ:κ ratio), including nociceptin, or by measuring opioid ratios in any blood cell, body fluid, or tissue other than peripheral blood. Applicants have not provided any guidance or working examples that determining any κ:κ ratios, including the use of nociceptin, would be indicative of an opioid-based pruritis, nor have Applicants provided any guidance or working examples demonstrating that measuring opioid ratios in blood cells, body fluids, or tissue would be indicative of a pruritis-based disease. In the absence of this guidance and working examples, it would not be predictable

to the artisan that a κ:κ peptide ratio, as well as any blood cell, body fluid, or tissue, could be used to determine whether or not a disease is opioid-based. It is believed that all pertinent arguments have been addressed.

***4. Conclusion***

A. No claim is allowable.

This is a continuation of applicant's earlier Application No. 09/704,319. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 05, 2004